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10/701,698	11/05/2003	Ricardo Blank	8496-US	7089

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Nestle HealthCare Nutrition
12 Vreeland Road, 2nd Floor, Box 697
Florham Park, NJ 07932

EXAMINER	
MARCETICH, ADAM M	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

athena.pretory@us.nestle.com
patentdepartment@rd.nestle.com

Office Action Summary	Application No.	Applicant(s)	
	10/701,698	BLANK ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,7,8,11-30 and 33-36* is/are pending in the application.

4a) Of the above claim(s) *25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,7,8,11-24,27-30 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 August 2009 has been entered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. 0226730.0, filed on 18 November 2002 in the United Kingdom has been filed. Therefore, a priority date of 18 November 2002 is given to claims 2,3,7,8 and 10-36.

35 USC § 112, 6th Paragraph

3. Regarding Applicant's:

- "first means for threadably attaching" of claims 2, 20, 21, 24 and 29,
- "second means for opening" of claims 2 and 3,
- "third means for fixedly attaching" of claim 2,
- "attachment means for fixedly attaching" of claims 7, 8, 27 and 28,
- "first venting means for venting" of claims 10 and 11,
- "second venting means" of claim 12,

- "dosing means for controlling" of claim 16,
- "first rim means" of claims 30, 31 and 33,
- "second rim means" of claims 30, 32 and 34-36,

4. the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

(A) The claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

5. Regarding claims 2, 3, 7, 11 and 16, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification.

6. Regarding claims 8, 12, 20, 21, 24 and 27-30 and 33-36, Applicant appears to not meet the requirements set forth in MPEP §2181, because the claims contain sufficient structure, material or acts for achieving the specified function.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 30 and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Allanson, Gary R. et al. (US 20030226855).

9. Regarding claim 30, Allanson discloses a connector device (¶ [0008], [0021], Fig. 1, self-sealing dispensing tap), comprising:

10. a rigid tube part (¶ [0021], Fig. 1, elongate tube 10);

11. a first end sealingly attachable to a feeding line (¶ [0021], Fig. 1, top of tube 10 capable of attaching to feeding line; also ¶ [0040], “exposed end of tap may be connected to dispensing apparatus tubing”); and

12. a second end sealingly attachable to a package (¶ [0029], Figs. 1, 3, 10, bottom end of tube 10 for sealing to package 100);

13. said rigid tube part having at about said second end a first rim means comprising a rigid material (¶ [0038], [0039], Fig. 10, tube 10 having clamp ring 60 threaded, suggesting rigid material); and

14. a second rim means comprising a flexible material more distal thereon (¶ [0038], [0040], Fig. 10, resilient seal 70 made of silicone);

15. said rigid tube part having at said second end a spike (¶ [0021], Fig. 1, piercing tip 12);

16. wherein, upon engagement of said connector device to a top portion of said package, said spike penetrates said top portion of said package (¶ [0021], [0029], Fig. 3, piercing tip 12 piercing container 100); and

17. wherein, upon engagement of said connector device to said top portion of said package, said first rim means engages the outer surface of said top portion of said package (¶ [0039], [0041], Fig. 10, clamp ring 60 seated on non-piercing end of tube 10 and placed outside container 100); and

18. said second rim means engages a corresponding inner surface of said top portion of said package (¶ [0040], Fig. 10, seal 70 pulled through container 100 wall and pressed against interior); and

19. sealingly attaching said connector device to said package between said first and second rim means (Fig. 10, wall of container 100 placed between ring 60 and seal 70, sealing tube 10).

20. Allanson also discloses an embodiment where the first and second rim means are provided as a single sterile package with pre-positioned components (¶ [0041]).

21. Regarding claims 33-36, Allanson discloses a connector device wherein:

22. [33] said first rim means is a flange (Fig. 10, clamp ring 60 forming flange-shape);

23. [33] said flange sealingly engaging the outer surface of said top portion of said package upon engagement of said connector device to said package (¶ [0039], [0041], Fig. 10, clamp ring 60 sealing outside container 100);

24. [34] said second rim means is a flexible flange (¶ [0038], [0040], Fig. 10, resilient seal 70 made of silicone);

25. [34] said flexible flange sealingly engaging the inner surface of said top portion of said package upon engagement of said connector device to said package (¶ [0040], Fig. 10, seal 70 pressed against interior of container 100); and

26. [35] said second rim means is a recess portion on said rigid tube part (Fig. 10, resilient seal 70 forming gap for wall of container 100 to fit between ring 60 and seal 70);

27. [35] said connector device sealingly engaging the inner surface of said top portion of said packaging along said recess portion upon engagement of said connector device to said package (Fig. 10, wall of container 100 placed between ring 60 and seal 70);

28. [36] said second rim means is a thickened portion on said rigid tube part (Fig. 10, seal 70 extending outwards from tube 10 and therefore forming thickened portion);

29. [36] said connector device sealingly engaging the inner surface of said top portion of said package along said thickened portion upon engagement of said connector device to said package (¶ [0040], Fig. 10, seal 70 pressed against interior of container 100).

Claim Rejections – 35 USC § 103

30. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

31. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

32. Claims 2,3,7,8,11,13,17,19,24,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533), in view of Allanson, Gary R. et al. (US 20030226855). Rationales and arguments are arranged in order of claim dependence.

33. Regarding claims 2 and 7, Kawaguchi discloses a connector device for connecting a feeding line of an enteral administration set to a laminated paper packaging system containing a composition (¶ [0027], Figs. 1, 5, adapter body 12 / 112 connecting to pack 20), the connector device comprising:

34. a rigid tube part being adapted to sealingly attach to the feeding line of the enteral administration set (¶ [0038], Fig. 5, annular ridges JR connecting to tube 30);

35. the tube part defining a first part of a passageway allowing the flow of the composition contained in the laminated paper packaging system to the feeding line of the enteral administration set (¶ [0057], Fig. 5, upper part of passage 112g connecting to tube 30);

36. first means for threadably attaching the rigid tube part to the laminated paper packaging system, whereby the connector is screwed to the laminated paper packaging system (¶ [0049], Fig. 5, annular member 112b threadably attaching adapter body 112 to linking member 114 on pack 20);

37. the first means further defining a second part of the passageway when threadably attached to the laminated paper packaging system (Fig. 5, lower part of passage 112g below annular rim 112b); and

38. second means for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system (¶ [0049], [0051], Fig. 5, pointed end 112a).

39. Kawaguchi discloses the invention substantially as claimed, see above. However, Kawaguchi lacks venting means as claimed [claims 2 and 7]. Evans discloses

a medical liquid dispenser (col. 1, lines 1-5, 30-42, Fig. 1, outlet member 18) comprising:

40. a first venting means for venting an interior of the laminated paper packaging system (col. 2, lines 45-52, col. 3, lines 47-59, Fig. 2, ball check valve member 56). Evans balances the volumes of dispensed fluid with an equal volume of air. One would be motivated to modify Kawaguchi with the venting means as taught by Evans to restore volume to a laminated package since a partial vacuum will prevent fluid from passing to a patient. That is, if air is not returned to a supply container, the reduced pressure within the container will prevent liquid from flowing effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi as discussed with the venting means as taught by Evans in order to dispense fluid effectively and prevent a vacuum.

41. Kawaguchi in view of Evans discloses the invention substantially as claimed, see above. However, Kawaguchi in view of Evans lacks third means for fixedly attaching as claimed [claim 2]. Allanson discloses a connector device (¶ [0008], [0021], Fig. 1, self-sealing dispensing tap), comprising:

42. a rigid tube part (¶ [0021], Fig. 1, elongate tube 10);

43. a third means for fixedly attaching a rigid tube part to a laminated paper packaging system (¶ [0038], [0040], Fig. 10, resilient seal 70);

44. whereby the connector device is secured to an interior surface within the laminated paper packaging system (¶ [0040], Fig. 10, seal 70 pulled through container 100 wall and pressed against interior).

45. Allanson seals the interior of a fluid dispensing system to prevent leaks and provide a hermetic sealing apparatus. With an interior seal, Allanson simultaneously reinforces a seal mechanically against stresses and fluidically against leaks (¶ [0008]). One would be motivated to modify Kawaguchi in view of Evans with the third means for fixedly attaching as taught by Allanson to secure a rigid tube, since each of the immediate invention, Evans and Allanson connect a tapper or spigot to a feeding line. When dangling from a support pole, a feeding line needs to resist tugging forces from a moving patient or from a caregiver repositioning the line.

46. Regarding claim 24, Kawaguchi discloses a connector device wherein:

47. the laminated paper packaging system includes a first surface with a frame-like member defining an annular threaded projection (¶ [0049], [0050], Fig. 5, linking member 114 attached to pack 20, defining cylindrical component 114a with male threads 14s); and

48. wherein the first means comprises a threaded annular portion complementary to the threaded projection of the laminated paper packaging system (¶ [0050], Fig. 5, annular member 112b threading to cylindrical component 114a).

49. Regarding claim 3, Kawaguchi discloses a second means comprising a cutting member protruding from the connector device in a direction towards the laminated paper packaging system for cutting the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system (¶ [0049], [0051], Fig. 5, pointed end 112a).

50. Regarding claims 13 and 19, Kawaguchi discloses a prefabricated enteral administration system comprising

51. an enteral administration set (¶ [0027], [0032], Figs. 1, 5, tube 30); and

52. a connector device non-releasably connected to the enteral administration set (¶ [0032], Figs. 1, 5, adapter body 112 connecting to tube 30).

53. Examiner interprets the connection between tube 30 and ridges JR as a "non-releasable" attachment, since a specific amount of force is required to separate the components (¶ [0038]). That is, tube 30 and ridges JR will not detach during normal use unless a user pulls the tubes forcefully. Kawaguchi discloses the invention as substantially claimed; see above. However, Kawaguchi lacks a third means for fixedly attaching as claimed [claims 2, 13 and 19]. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Allanson.

54. Regarding claim 17, Kawaguchi discloses an enteral administration kit comprising:

55. an enteral administration set (¶ [0027], [0032], Figs. 1, 5, tube 30); and

56. a laminated paper packaging system containing a composition to be enterally administered to a patient (¶ [0028], [0049], Fig. 5, pack 20). Examiner cites Allanson to remedy the deficiencies of Kawaguchi, namely a third means for fixedly attaching a rigid tube part. See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi in view of Allanson.

57. Regarding claim 27, Kawaguchi in view of Evans discloses the invention as substantially claimed, including an adhesive layer of Kawaguchi (¶ [0058], Fig. 5,

adhesive layer 114c). However, layer 114c of Kawaguchi engages the first surface of a package before a spike penetrates the package. Therefore, Kawaguchi lacks an adhesive layer having the claimed function [claim 27].

58. Allanson discloses an attachment means comprising a sealing member that engages the first surface of the laminated paper packaging system subsequent to penetration of the first spike (¶ [0039], [0041], Fig. 10, clamp ring 60). One would be motivated to modify Kawaguchi, Evans and Allanson by including an adhesive layer as taught by Kawaguchi on clamp ring 60 of Allanson to attach a connecting member to a package, since the adhesive layer performs the same function of securing a connector member to a package in both cases. That is, Allanson calls for secure sealing between a connecting member and package by including clamp ring 60 on the connecting member.

59. Regarding claim 28, Kawaguchi in view of Evans discloses the invention as substantially claimed, including adhesive layer 114c; see above. However, Kawaguchi in view of Evans lacks a first annular rim as claimed [claim 28]. Allanson discloses a first annular rim (¶ [0039], [0041], Fig. 10, clamp ring 60). See discussion of claim 27 above regarding rationale and motivation to apply an adhesive layer as taught by Kawaguchi to the ring 60 of Allanson.

60. Regarding claim 8, Kawaguchi discloses a connector device wherein the first spike defines a point (¶ [0049], [0051], Fig. 5, pointed end 112a). Kawaguchi in view of Evans discloses the invention as substantially claimed; see above. However, Kawaguchi in view of Evans lacks first and second rims as claimed [claim 8].

61. Allanson discloses a connector wherein:

62. a first rim of the attachment means is formed of a rigid material and is located a first distance from the point of the first spike (¶ [0038], [0039], Fig. 10, tube 10 having clamp ring 60 threaded, suggesting rigid material); and

63. the attachment means further comprises a second rim on the spike formed of a flexible material and located a second distance from the point of the spike (¶ [0038], [0040], Fig. 10, resilient seal 70 made of silicone);

64. the second distance being less than the first distance (Fig. 10, distance between resilient seal 70 and piercing tip 12 less than distance between clamp ring 60 and tip 12).

65. Allanson reinforces a tube both mechanically and fluidically with the combination of a rigid first rim and flexible second rim. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Evans in view of Allanson.

66. Regarding claim 11, Kawaguchi discloses the invention as substantially claimed. However, Kawaguchi lacks a valve means as claimed [claim 11]. Evans discloses a first venting means comprising a valve means allowing air to enter through the valve means while preventing the composition to be administered to exit (col. 2, lines 45-52, col. 3, lines 47-59, Fig. 2, ball check valve member 56). Evans balances the volumes of dispensed fluid with an equal volume of air. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Evans.

67. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533) in view of Allanson, Gary R. et al. (US 20030226855), further in view of Quinn; David G. et al. (US 4921138).

68. Regarding claim 12, Kawaguchi, Evans and Allanson disclose the invention substantially as claimed, see above. However, Kawaguchi, Evans and Allanson lack a visualization tube and second venting means as claimed [claim 12]. Quinn discloses an enteral fluid dispenser (col. 2, lines 51-55, col. 5, lines 25-34, Fig. 1, fluid dispensing device 24) for connection to a laminated paper package (col. 1, lines 35-39), further comprising:

69. a visualization tube (col. 5, lines 25-34, Fig. 1, column 26);

70. one end of the visualization tube being connected to a passageway for the composition to be administered (col. 5, lines 50-55, Fig. 3, spike 58 connecting to lowermost corner 18); and

71. the other end of the visualization tube being connected to a second venting means (col. 5, lines 25-34, Figs. 1, 3, venting port 32);

72. the second venting means comprising an air inlet and a second spike adapted to penetrate a second surface of the laminated paper packaging system corresponding to a predetermined fluid level of the composition (col. 5, lines 25-34, 50-55, Figs. 1, 3, venting port 32 in fluid communication with spike 56). Quinn displays the remaining level of nutrient solution (cols. 6-7, lines 64-2) while preventing a vacuum from forming inside

a supply package (col. 5, lines 25-34). One would be motivated to modify Kawaguchi, Evans and Allanson with the visualization tube and second venting means as taught by Quinn to display a level of nutrient solution since this prevents solution from being wasted. Kawaguchi calls for conserving nutrient solution by dispensing all remaining fluid (¶ [0054], Fig. 7, discharge hole DH dispensing all fluid from container). Showing whether a fluid remains in a supply package prevents it from being wasted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Evans and Allanson as discussed with the visualization tube and second venting means as taught by Quinn in order to prevent both a vacuum and wasted solution.

73. Claims 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533), in view of Allanson, Gary R. et al. (US 20030226855), further in view of Schafer (US 5993422).

74. Regarding claims 14 and 16, Kawaguchi, Evans and Allanson disclose the invention substantially as claimed, see above. However, Kawaguchi, Evans and Allanson lack a pump unit or dosing means as claimed [claims 14 and 16]. Schafer discloses a device for dosing enteral fluids (col. 1, lines 44-47) from a laminated container (col. 4, lines 41-46, Fig. 5, container 29), comprising a pump unit arranged in the feeding line of the enteral administration set. (col. 3, lines 54-59, Fig. 1, pump unit 2). Schafer delivers nutrients at variable rates, independent of the viscosity of a nutrient

solution (col. 2, lines 12-16 col. 3, lines 10-16). Additionally, Schafer delivers these nutrients independent of the level of nutrient solution remaining in a container. One would be motivated to modify Kawaguchi, Evans and Allanson with the dosing means as taught by Schafer to deliver solution accurately since a viscous solution may require additional force to dispense it to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi in view of Rule as discussed with the dosing as taught by Schafer in order to dispense viscous solutions at a precise rate.

75. Regarding claim 18, Kawaguchi discloses an enteral administration kit comprising:

76. an enteral administration set (¶ [0027], [0032], Figs. 1, 5, tube 30); and

77. a laminated paper packaging system containing a composition to be enterally administered to a patient (¶ [0028], [0049], Fig. 5, pack 20). Examiner cites Evans and Allanson to remedy the deficiencies of Kawaguchi. See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi in view of Evans and Allanson.

78. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533), in view of Allanson, Gary R. et al. (US 20030226855), further in view of Broman; Cyrus R. (US 2969063).

79. Regarding claim 15, Kawaguchi, Evans and Allanson disclose the invention substantially as claimed, see above. However, Kawaguchi, Evans and Allanson lack an

intermediate bag as claimed [claim 15]. Broman discloses a parenteral fluid set (col. 1, lines 15-19, 63-70, Fig. 1, administration set) comprising a transparent intermediate bag (col. 2, lines 19-26, Fig. 1, device 22 made of translucent PVC). Broman accurately delivers discrete amounts of fluid to a patient by clamping portions of an intermediate bag (cols. 3-4, lines 73-6, 27-29). One would be motivated to modify Kawaguchi, Evans and Allanson with the intermediate bag as taught by Broman to accurately dispense small volumes since a supply package may contain more solution than a patient will consume at a single meal. Additionally, Broman allows a caregiver to record the volumes of solution that a patient consumes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Evans and Allanson as discussed with the intermediate bag as taught by Broman in order to dispense fractional amounts of a supply container and accurately record the volumes a patient consumes.

80. Claims 20-23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007) further in view of Ninomiya; Satoru et al. (US 5141133).

81. Regarding claim 20, Kawaguchi in view of Rule discloses the invention substantially as claimed, see above. including a rigid tube part, first means for threadably attaching, first and second parts of a passageway and a cutting member. See above. However, Kawaguchi in view of Rule lacks a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first

threaded portion of a packaging system as claimed [claim 20]. In other words, pointed end 112a of Kawaguchi cuts a surface before engagement of a first means.

82. Ninomiya discloses a pouring plug for piercing a laminated beverage pack (col. 3, lines 28-31, col. 4, lines 13-19, pouring plug for mounting to container wall 18). Ninomiya demonstrates a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first threaded portion of a packaging system (col. 4, lines 6-12, Fig. 3, tubular blade 12 not projecting from lower opening of tubular body 1 after mounting to threaded mounting portion 10). Here, Ninomiya prevents premature rupture of a sealed container (col. 6, lines 44-49, especially lines 56-59). In this rejection, Examiner shortens the lower portion of adapter body 112 of Kawaguchi to allow pointed end 112a to pierce pack 20 only after annular member 112b engages linking member 114. Alternatively, Examiner lengthens cylindrical component 114a for the same purpose. One would be motivated to modify Kawaguchi in view of Rule with the dimensions of a cutting member as taught by Ninomiya to prevent premature rupture that would create a leak.

83. Regarding claim 21, Kawaguchi discloses a cutting member integrally formed with the first means (Fig. 6, pointed end 112a formed integrally as part of adapter body 112).

84. Regarding claims 22 and 23, Kawaguchi discloses a prefabricated enteral administration system comprising:

85. [22] an enteral administration set and a connector device non-releasably connected to the enteral administration set (¶ [0032], Figs. 1, 5, adapter body 112 connecting to tube 30); and

86. [23] a laminated paper packaging system containing a composition to be enterally administered to a patient (¶ [0028], [0049], Fig. 5, pack 20).

87. Kawaguchi discloses the invention substantially as claimed, see above. Examiner cites Rule to remedy the deficiencies of Kawaguchi, namely a first means that also fixedly attaches the rigid tube part to an interior surface of the laminated paper packaging of claim 20.

88. Regarding claim 29, Kawaguchi discloses a connector device wherein:

89. the first means includes a second threaded portion defined on the connector device (¶ [0049], [0050], Fig. 5, cylindrical component 114a having male threads 14s); and

90. the second threaded portion being complementary to the first threaded portion of the frame-like member of the laminated paper packaging system such that the connector device threadably engages the frame-like member of the laminated paper packaging system (¶ [0050], Fig. 5, annular member 112b threading to cylindrical component 114a).

Response to Arguments

91. Applicant's arguments, see p. 9-15 filed 17 August 2009 regarding the rejection(s) of claim(s) 2,3,7,8,11-19, 24, 27, 28, 30 and 33-36 under 35 USC § 103 over Kawaguchi '246, Rule '007, Ninomiya '133, Schafer '422, Broman '063, Evans '533 and Quinn '138 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. Arguments regarding the rejection(s) of claim(s) 20-23 and 29 over Kawaguchi '246, Rule '007 and Ninomiya '133 have been fully considered but are not persuasive. Upon further consideration, a new ground(s) of rejection is made under 35 USC § 102 and 103 over Allanson '855, Kawaguchi '246, Rule '007, Ninomiya '133, Schafer '422, Broman '063, Evans '533 and Quinn '138.

92. Applicant contends that Kawaguchi and Rule lack a first rigid rim and second flexible rim. Examiner cites Allanson as teaching the first and second rim means in the new grounds of rejection.

93. Applicant submits that Evans fails to remedy the deficiencies of Kawaguchi and Rule, namely a first venting means. Examiner notes that new grounds of rejection are provided over Kawaguchi in view of Evans in view of Allanson.

94. Applicant notes that Kawaguchi discloses an elongated pipe adapter completely enclosed by a tube, that Rule discloses top and bottom portions completely enclosed by a teat and a container, and reasons that the tubing of Kawaguchi or teat of Rule would completely cover the vent of Evans. Applicant also requests that the Examiner clarify the rejection of Kawaguchi in view of Evans.

95. Examiner notes that Evans also discloses a tube completely enclosed by a container and tube, namely fluid outlet passageway 36. To vent air, Evans places another lumen with one end inside a container and the other outside (Fig. 2, air inlet 38). Adding a second lumen to the dispenser of Kawaguchi does not destroy its function, and allows for all contents to be dispensed. Additionally, this modification inverts the outlet member 18 of Evans, to face air inlet 38 towards a container and filter 58 away from a container. Kawaguchi calls for a venting means, since Kawaguchi suggests a need to entirely dispense the contents of a container (¶ [0014], discharge opening or groove for discharging residual liquid, to avoid wasting contents). Lastly, the vented tube of Kawaguchi in view of Evans is surrounded by clamp ring 60 and resilient seal 70 of Allanson in the new grounds of rejection. These components are adapted to surround a tubular structure, as depicted in Figs. 1 and 10 of Allanson.

96. Applicant submits that Ninomiya fails to remedy the deficiencies of Kawaguchi and Rule, namely a cutting member as claimed [claim 20]. Applicant notes that Ninomiya discloses that only saw tooth blade 12a ruptures a container surface, and that most of the tubular body 1 and lid 2 do not enter the container. Applicant reasons that a skilled artisan would not shorten the bottom pointed end of the elongated pipe adapter body in Kawaguchi or the bottom spike of the tubular teat mounting of Rule in view of Ninomiya, because to do so would render the devices of Kawaguchi and Rule inoperable. Examiner notes that Ninomiya does not render the combination inoperable since each of Kawaguchi and Rule require only that a tube extend into a container far enough to withdraw liquid. That is, a tube that extends a shorter distance into a

container does not prevent liquid from being dispensed. Additionally, Kawaguchi suggests that a shorter tube may be preferable, since a longer tube requires an opening or groove for discharging residual liquid (¶ [0014]).

97. Applicant submits that Quinn, Schafer and Broman fail to remedy the deficiencies of Kawaguchi and Rule. To clarify, Examiner cites:

- Quinn as teaching a visualization tube and second venting means;
- Schafer as teaching a pump unit or dosing means; and
- Broman as teaching an intermediate bag.

Conclusion

98. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- McKitrick; Robert US 6932239
- Schroeder; Charles W. US 6651845
- Reddy; Balakrishna et al. US 6378730
- McDonough; Charles M. et al. US 5971207
- Dirksing; William P. US 5125886
- Kato; Noriyoshi US 3973698

99. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich
Tel 571-272-2590
Fax 571-273-2590

100. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

101. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

102. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
5 October 2009